

Implementation of a large Atlas system at Glaxo Wellcome

Glaxo Wellcome, one of the world's largest pharmaceutical companies, was formed in the 1995 merger of Glaxo and Wellcome (Burroughs Wellcome in the US). As one would expect in the blending of two thriving organizations, there were different systems and working practices in the two individual organizations which the combined company needed to consolidate. One of those areas of difference was chromatography data systems.

Company:
Glaxo Wellcome
Industry Sector:
Pharmaceutical
Environment:
**Pharmaceutical
Development, Chemical
Development,
BioAnalysis, Drug
Metabolism**
Software Used:
Atlas
Platform:
Windows NT®

unifying working practices began, the different chromatography systems were a significant barrier to success. The company faced-

- incompatible infrastructure and building wiring
- great difficulty in moving staff from one laboratory to another
- the need to retrain large numbers of users on different systems
- features viewed as essential that were available on one system but not on another
- extra hurdles in transferring analytical methods from one group to another in the same department.

Glaxo Wellcome's development work is centered at four sites in the UK (Ware, Stevenage, Dartford and Beckenham) and one in the US (Research Triangle Park, NC, where both Glaxo and Burroughs Wellcome had their US headquarters). Following the merger, development scientists at these sites had about 1100 chromatography channels (detectors), and the data was being acquired and processed in three different data systems. As the important task of harmonizing and



Identifying the need for a global, corporate standard CDS



There were other problems with all three of the existing chromatography data systems: old computers with diminishing support, both internally and externally, for their hardware and operating systems; cumbersome user interfaces; arcane terminal emulators and other specialized software on each desktop computer; and a chromatography support group that was stretched to the limit trying to keep up with

user training, system support, validation, and archiving on three systems at multiple sites in two countries.

All of these problems were a drain on the productivity of the development scientists and the chromatography support staff. Accordingly, a team was formed in early 1996 to identify a

chromatography data system that could become the corporate standard.

This project culminated in Glaxo Wellcome joining LabSystems and a number of other customer companies in a Joint Application Development project to produce a new chromatography data system. The result of this project, Atlas, was launched in January 1998.

The implementation scope

This case study describes the project planning and approach taken to deploy Atlas to some 500 scientists working at Glaxo Wellcome. In both the United States and the United Kingdom, the implementation scope of the project was split into three main phases

Phase 1 - Implement Atlas for 300+ scientists in the US & UK Pharmaceutical Development departments.

Phase 2 & 3 - Implement Atlas for 200+ scientists in the US & UK Chemical Development and BioAnalysis and Drug Metabolism departments.



Project organization

For the project initiation Glaxo Wellcome had first to justify the project in order to obtain Information Systems resources and, of course, capital funding. Justification was based on business benefits and costs over a 7-year life cycle of the system. Also part of the project initiation was the phase 1 implementation plan, consisting of the project organization, responsibilities, deliverables and milestones.

For such a large project, particularly one based both in the USA and UK, together with the added complexity of deploying into a regulated environment, it is important to properly resource and organize a number of project teams.

An Atlas Steering Group was responsible for all major decisions in the project. This group of 15 people was tasked with the success of the project within Glaxo Wellcome and consisted of Pharmaceutical Development project leaders, IS project managers, IS and user representatives and a validation compliance representative.

The actual day to day project work was the responsibility of a 19 strong project team, some members of which had multiple roles consisting of

- Validation - Pharmaceutical Development lead with 5 US and 2 UK representatives
- Training - IS lead with 4 US and 8 UK representatives
- Reporting - IS lead with 2 US and 1 UK representative
- Configuration - IS lead with 2 US and 1 UK representative

Implementation planning started in early 1998, with continued testing of Atlas and project planning taking place for most of this year. Towards the end of 1998, Atlas 98 Service Pack 1 was accepted by Glaxo Wellcome for full deployment.



The Validation Team

A critical component of the Atlas project plan in Glaxo Wellcome was the validation of the system for use by Pharmaceutical Development, a GLP/GMP regulated environment. There were a number of issues the validation team had to deal with. Glaxo Wellcome wanted a single international validation of Atlas. Once achieved, this would significantly reduce the cost of ownership for Glaxo Wellcome by avoiding repeated local country validations. It would also minimize the time taken to deploy Atlas throughout the organization. One benefit of Atlas, and a key result of the Joint Application Development approach, was the in-parallel development of an Atlas Automated Installation Qualification toolkit, and an extended automated Validation kit.

These tools were developed alongside the main development of the Atlas software and are both subsets of the automated tests which the Atlas development team use as part of LabSystems internal validation.

The main tasks of the Glaxo Wellcome validation team were to

- Write a master validation plan
- Assess the viability and use of the LabSystems Installation Qualification and Validation kit
- Verify all key calculations
- Write additional Glaxo Wellcome validation tests to fill gaps and to test Glaxo Wellcome specific add-ons.
- Execute the IQ, Validation kit and Glaxo Wellcome test cases
- Write a final validation report

The Training Team

The Training Team had the task of developing and deploying user training in phase 1 to some 300+ busy scientists, a considerable task. To minimize downtime and impact on the productivity of Glaxo Wellcome's scientists, it was necessary to develop a condensed one day Atlas course specifically designed for Glaxo Wellcome's needs; the standard LabSystems Atlas class lasts three days.

The Training Team split their task into a number of items. The first was to develop pre-class tutorials for attendees to read before attending the first classroom session. The team then developed and produced a number of "Quick Start" guides covering common tasks such as Starting a Run and Calibration and Quantitation. These could be taken away by class attendees for easy reference following the course itself. Finally the team had to develop the course itself. This was loosely based on the training course collateral developed by LabSystems. It was decided

to divide the course into two half-day sessions

Session 1

- Acquisition
- Automatic and manual integration
- Peak identification

Session 2

- Calibration and Quantitation
- Reports

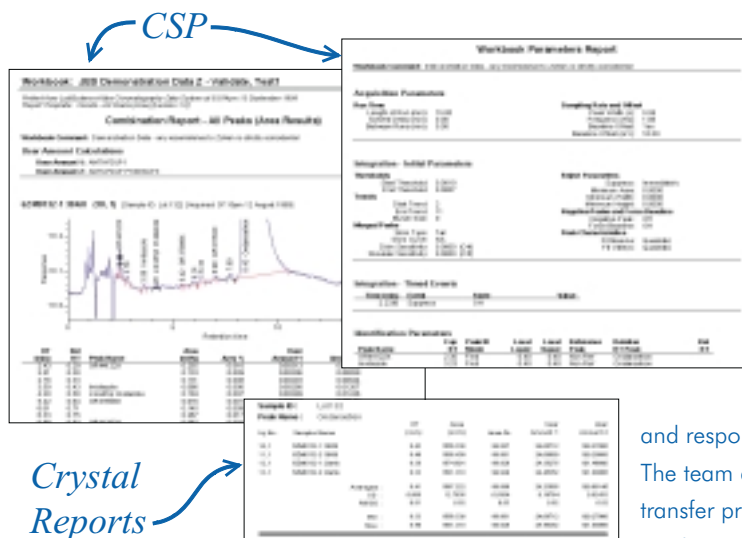
The collage features several training documents. At the top left is a document titled 'Atlas Tutorial'. In the center is a 'Starting a Run' guide with a numbered list of steps: 1. Create a new workbook from a template or an existing; 2. Add one row per sample (Insert->Samples); 3. Name the samples now or later; 5. Save; 6. Start run. Below this is a 'Skimming Small Peaks' slide with a list of criteria: Skim Sensitivity, Fraction of parent peak's height (0-1), All riders smaller than that fraction will be skimmed, and Zero means never skim. To the right of the slide is a chromatogram showing a large peak and a smaller peak, with a bracket indicating a fraction of 0.45. At the bottom right of the slide is the number '11' and a small '8'.

Beginning several weeks after the training class, attendees were invited to "lunch and learn" sessions to address questions and special topics.

The Reporting Team

The Reporting Team had the task of designing standard reports needed by the scientists. There were two issues which the team had to address:-

- The standard Atlas reports did not meet all the users needs, and
- No single reporting method (Atlas ReportManager, Atlas CSP reporting language nor Crystal Reports) could create all the reports needed.

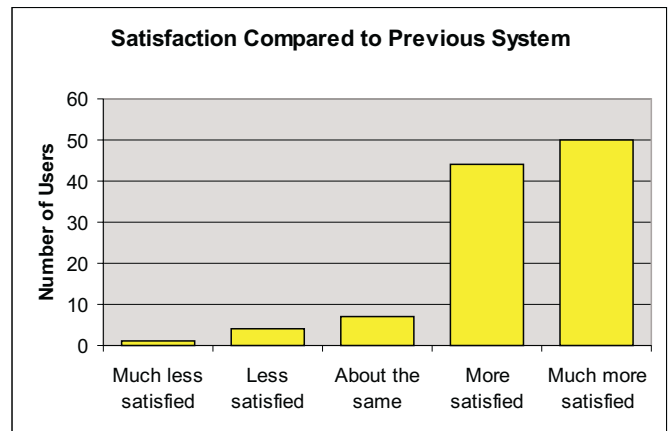


Customer Satisfaction

Following the completion of the phase 1 deployment, the project team conducted a survey of the users of Atlas. Over 90% were either more satisfied or much more satisfied with Atlas compared to their previous system and over 80% reported they were either more productive or much more productive with Atlas compared to their previous system.

Phase 1 isn't totally complete, the quantitative and qualitative business benefits are being measured, the old systems need to be decommissioned and a final report must be prepared for management. Future plans include implementing phases 2 &

3 in the rest of Development, implementing new versions of Atlas to take advantage of bug fixes and enhancements from LabSystems, and providing additional reports, archiving capabilities and home access.



Conclusions

Testing, validating and implementing such a large system in a regulated environment is a complex IT project in its own right. This was successful at Glaxo Wellcome due to a properly resourced team that involved all stakeholders. The validation collateral developed by LabSystems together with customers such as Glaxo Wellcome had a particularly beneficial impact on reducing the time and effort to validate the system. On completion of Phase 1 deployment, users reported improved productivity and satisfaction with the system compared to their previous system.

Thanks to...

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